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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,453	04/12/2007	Chris Dykes	027027.077100	2102

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EXAMINER	
PREGLER, SHARON	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,453	DYKES ET AL.	
	Examiner	Art Unit	
	Sharon Pregler	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I claims 1-21 in the reply filed on February 22, 2010 is acknowledged.

Claim Objections

1. ***Claim 16*** is objected to because of the following informalities: "wth" on line 2 of the claim is misspelled.

2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. ***Claims 6, 9, & 16*** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 6 & 9, the term "an open-ended chamber that is sealed by insertion between sensor walls of said analyzer," is unclear as to what the specific chamber is.

6. Regarding claim 16, the term: "to guarantee disposable is located," it is unclear what specific object this phrase entails. For the purposes of this action, it is interpreted as the blood sample collection device.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. ***Claims 1-12, 14, & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lauks et al. 5,096,669 (hereinafter "Lauks").***

9. **Regarding claim 1, Lauks teaches a fluid** sample collection device *(self-contained disposable sensing device 10)* for collecting 0.05 mL or less of blood *(column 3 lines 15-20)*, and for insertion and testing of said blood in an analyzer *(reader 150)*, comprising:

10. a thin elongate body *(body figure 2)* having a finger-grip at one end *(uneven shape of the device depicted in figure 3 effectively facilitates handling)*, and another functional insertion end *(slotted opening 360, column 4 lines 20-25)*, said insertion end including,

11. a collecting region *(second conduit 224 to capillary break 222, column 3 lines 15-20)* including an entrance aperture *(orifice 108)* through which fluid enters the device by capillary action and flows into said collecting region *(column 4 lines 48-51)*,

12. a testing region *(third conduit 228 to sensing arrays 66, column 4 lines 40-43)* in fluid communication with said collecting region for containing said fluid during testing inside said analyzer *(column 4 lines 25-30)*, and

13. a pumping region *(third cavity 22 serves as air bladder 229; when air bladder is depressed, air is forced down a fourth conduit 234 into second conduit 224)* in fluid communication with said testing region for introducing a pressure-differential *(column 4 lines 43-45)* and thereby inducting said fluid from said collecting region into said testing region for testing *(See figures 2-3 column 4 lines 35-50)*.

14. **Regarding claim 2, Lauks teaches the** fluid sample collection device according to claim 1, wherein said pumping region comprises a bulb *(air bladder 229 formed by cavity 22 and adhesive sheet 74, column 10 line 12)* for introducing said pressure-differential.

15. **Regarding claim 3, Lauks teaches the** fluid sample collection device according to claim 1, wherein said pumping region *(air bladder region 229 & cavity 22 and adhesive sheet)* comprises an orifice for coupling a pump in said

analyzer to said testing region for introducing said pressure-differential *(column 10 lines 5-20)*.

16. **Regarding claim 4, Lauks teaches the** fluid sample collection device according to claim 2, wherein said bulb is operated by insertion of said collection device into said analyzer and squeezing thereof during insertion *(column 10 lines 5-20)*.

17. **Regarding claim 5, Lauks teaches the** fluid sample collection device according to claim 2, wherein said bulb is operated by squeezing via an actuator in said analyzer *(column 10 lines 5-20)*.

18. **Regarding claim 6, Lauks teaches the** fluid sample collection device according to claim 1, wherein said testing region comprises an open-ended chamber *(cavity 18, figure 3, column 5 lines 39-60)* that is sealed by insertion between sensor walls of said analyzer.

19. **Claim 7 recites** "means for collecting a fluid sample by capillary action." The Applicant's specification supports and illustrates in figure 1 and [0010]-[0011] & [0043]: A blood sample from a finger stick is dripped onto and collected in the pick-up area of the test sensor. If the pick-up area volume is filled, an amount of blood required for testing will necessarily flow by capillary action through a transfer area and into a read area containing a reagent, where the monitoring unit reads the results. Accordingly, this means-plus-function language invokes a 35 U.S.C. 112 6th paragraph limitation (see MPEP § 2181).

20. **Claim 7 recites** "means for transporting said fluid to a testing region by pressure-differential." The Applicant's specification supports and illustrates in figures 3-6, [0024] & [0045]: An integral pressure-differential actuator that is activated once the device is inserted into analyzer to cause blood to flow between the capillary collection tube and the testing chamber. Accordingly, this means-plus-function language invokes a 35 U.S.C. 112 6th paragraph limitation (see MPEP § 2181).

21. **Regarding claim 7, Lauks teaches a** fluid sampling device, comprising:

22. means for collecting a fluid sample by capillary action *(column 9 lines 57-61)*; and

23. means for transporting said fluid to a testing region by pressure-differential for testing by an analyzer *(calibrant fluid flows out of pouch 60*

through first conduit 220 into third conduit 238 and then across sensing arrays 68, column 10 lines 5-20) (air bladder forces fluid to move past capillary break 222; apertures expose sensing arrays, column 9 lines 20-25).

24. **Regarding claim 8, Lauks teaches the** disposable blood sample collection device *(self-contained disposable sensing device 10)* for insertion and testing of a blood sample *(column 3 lines 15-20)* in a portable analyzer *(reader 150)*, comprising:

25. an elongate body *(body figure 2)* including,

26. a collecting region *(second conduit 224 to capillary break 222, column 3 lines 15-20)* including an entrance aperture *(orifice 108)* through which blood is drawn into the device by capillary action *(column 4 lines 48-51)*,

27. a testing region *(third conduit 228 to sensing arrays 66, column 4 lines 40-43)* in fluid communication with said collecting region for exposing said blood sample to a sensor during testing inside said analyzer *(column 4 lines 25-30)*, and

28. an orifice *(calibrant fluid flows out of pouch 60 through first conduit 220 into third conduit 238 and then across sensing arrays 68, column 10 lines 5-20)* in fluid communication with said testing region for coupling a pump *(air bladder forces fluid to move past capillary break 222; apertures expose sensing arrays, column 9 lines 20-25)* inside said analyzer to induct said blood sample from said collecting region into said testing region for testing.

29. **Regarding claim 9, Lauks teaches the** fluid sample collection device according to claim 1, wherein said testing region comprises an open-ended chamber *(cavity 18, figure 3, column 5 lines 39-60)* that is sealed by insertion between sensor walls of said analyzer.

30. **Regarding claim 10, Lauks teaches a** disposable blood sample collection device for insertion and testing of a blood sample in a portable analyzer *(column 9 lines58-61)*, comprising:

31. an elongate body *(figure 2)* including,

32. a collecting region including an entrance aperture *(orifice 108)* through which blood is drawn into the device by capillary action *(column 9 lines 58-62)*,

33. a testing region in fluid communication with said collecting region for exposing said blood sample to a sensor during testing inside said analyzer *(column 9 lines 20-25, column 10 lines 5-20)*, and

34. a bulb *(air bladder 229 formed by cavity 22 and adhesive sheet 74, column 10 line 12)* in fluid communication with said testing region and manipulated by said analyzer to induct said blood sample from said collecting region into said testing region for testing.

35. **Regarding claim 11, Lauks teaches the** disposable blood sample collection device according to claim 10, wherein said bulb *(air bladder 229)* is manipulated by said analyzer *(column 10 lines 10-20)* as a result of insertion therein.

36. **Regarding claim 12, Lauks teaches the** disposable blood sample collection device according to claim 10, wherein said bulb is manipulated by an actuator inside said analyzer *(column 10 lines 10-20)*.

37. **Regarding claim 14, Lauks teaches a** disposable blood sample collection device *(self-contained disposable sensing device 10)* for insertion into an analyzer *(reader 150)*, comprising:

38. a thin elongate body adapted for insertion into said analyzer *(figure 1)*;

39. a capillary tube *(conduit 224, figure 2)* integrally-molded in said body and extending inwardly from a distal end *(extension in figure 2)*;

40. an open-sided testing chamber *(third conduit 228 to sensing arrays 66, column 4 lines 40-43)* in fluid communication with said capillary tube; and

41. an actuator region *(third cavity 22 serves as air bladder 229; when air bladder is depressed, air is forced down a fourth conduit 234 into second conduit 224)* in fluid communication with said testing chamber for introducing a pressure-differential *(column 4 lines 43-45)* and thereby inducting blood from said capillary tube into said testing chamber for testing *(calibrant fluid flows out of pouch 60 through first conduit 220 into third conduit 238 and then across sensing arrays 68, column 10 lines 5-20) (air bladder forces fluid to move past capillary break 222; apertures expose sensing arrays, column 9 lines 20-25)*.

42. **Regarding claim 16, Lauks teaches the** disposable blood sample collection device according to claim 14, wherein said thin elongate body comprises at least one edge which communicates with said analyzer to

guarantee disposable is located correctly with respect to said analyzer *(device inserted through opening 360, figures 11-13 column 10 lines 50-60)*.

Claim Rejections - 35 USC § 103

43. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

44. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

45. ***Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks et al. 5,096,669***.

46. **Regarding claim 13,** Lauks does not specifically teach a solenoid actuator. However, it is well known in the art that fluidic actuators may comprise a solenoid for the benefit of controlling fluid flow by converting electrical energy to mechanical energy. It would have been obvious to provide the device of Lauks et al. with a solenoid actuator to control fluid flow.

47. ***Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks et al. 5,096,669 in view of Kelley US Patent 5,257,984 (hereinafter "Kelley")***.

48. **Regarding claim 15, Lauks teaches the** disposable blood sample collection device according to claim 14, but does not teach said capillary tube is pre-loaded with anticoagulant.

49. However in the analogous art of blood collecting devices, Kelley teaches a glass capillary tube coated with anticoagulant for keeping the blood thin *(column 1 lines 50-60)*.

50. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an anticoagulant of Kelley in the capillary chambers of Lauks for keeping the blood thin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Pregler whose telephone number is (571)270-5051. The examiner can normally be reached on Mon - Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Pregler/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797